REMARKS

No amendments are made to pending claims 1, 3-20, 22, 24-26 and 28-31. These claims remain in the form presented in the amendment filed December 17, 2008.

In General

Shah et al. (US 6,984,215) is Not Relevant and is Not Prior Art in Any Event

The examiner cites the Shah et al. patent for the first time as showing perforations in Figs. 2A and 2B between sections 202a and 202b and at column 3, lines 8-14. However, the specification simply says that "The plurality of inflatable sections may be physically separated (either partially or fully) from one another." There is no indication that the dashed lines in Figs. 2A and 2B are lines of perforations.

In any event, the 5/28/04 filing date of the Shah et al. patent is **after** the 2/23/04 filing date of the present application. Further, the provisional application from which the Shah et al. patent claims priority does not disclose the dashed lines referred to the by the examiner. Accordingly, the Shah et al. patent is not entitled to the priority date of the provisional application for purposes of the subject matter relied on by the examiner. For this reason, applicants request that this reference be withdrawn as prior art. [1]

Separation by Tearing is not Equivalent to Separation Using Zippers, Hooks, etc.

The examiner makes the following assertion in the paragraph bridging pages 6 and 7 of the Office action:

> "Applicant argues that the achievement of the instant invention to provide a sequential compression sleeve which is intentionally designed to be separated into different parts as surprising and unpredictable however, both Rotta and Lee teach the heart of applicant's invention. There is no unobviousness to the exact way in which they are separated. The prior art teaches being torn apart as taught by Shah or cut apart as taught by Arkans or unzipped by Poole or snapped apart by Lee. They are all obvious equivalent alternative ways of doing the same thing. There is no unobviousness to any one of them. They all of their own well known characteristics [sic]."

[1] The only other prior art reference showing perforations is Islava US Pat. 6,719,711, but this patent is not relevant for at least the reasons given in prior responses and below.

Applicants respectfully (but strongly) disagree. There are fundamental differences between disconnection by tearing, as claimed by applicants, and disconnection by using mechanical quick-connect fasteners as shown in the Poole (zippers) and Lee (hooks).[2] Tearing along line of perforations **destroys** a connection between two parts. Once torn apart, the two parts cannot be reconnected. Using zippers, hooks, and the like, as taught by the cited art, **does not destroy** the connection between two parts. On the contrary, these types of mechanical fasteners form releasable connections that allow two parts, once separated, to be reconnected. Also, using a line of perforations instead of releasable mechanical connectors of the type shown in the cited prior art allows applicants' compression sleeve to be manufactured as a **one-piece** sleeve. As a result, the product is cheaper and easier to use because there is no need to connect, disconnect and/or re-connect a series of separate segments. If and when the need arises to shorten the sleeve, a portion is simply torn from the sleeve, and the sleeve continues to function, all without the need to manipulate releasable mechanical connectors.

Thus, there is no equivalence as contended by the examiner, and it is submitted that substituting a non-reusable connection for a reusable connection would not be obvious to the skilled person except in the hindsight of applicants' own disclosure.

Claim Rejections - 35 USC §103

Claims 1, 3-7, 11-13, and 18-20 are rejected under 35 USC 103 as unpatentable over either Rotta (US 3,862,629) or Lee et al. (US 3,826,249) in view of either Islava (6,719,711) and Shah et al. (US 6,984,215).

Rotta discloses a compression device in which a series of inflatable modular units can be plugged together using valve means 14 to make a compression device of any desired length. Lee et al. discloses an inflatable compression device that includes a series of inflatable wrappings which can be interlocked by hooks 16 to provide the desired length.

The Islava patent is directed to an inflatable splint which is used to immobilize a broken limb such as an arm. The Islava device has two or more rows of latitudinal air

[2] The examiner states on page 7 of the action that Arkans teaches parts being "cut apart", but there is no such disclosure in Arkans.

chambers 22 which are inflated by conventional blow spout 18. The rows of chambers are separated by perforated welds 40, 42 along which the splint may be torn partially across the splint to form two U-structures which can be used as shown in Figs. 3 and 4. The U-structures thus formed remain connected by a central hinge area 29 of the splint. Unlike applicant's claimed design where the perforations extend continuously across the sleeve to allow a first portion of the sleeve to be completely removed, the entire emphasis in Islava is toward only a partial tearing of the splint along the perforated weld 40, 42. In this way, a center portion 29 of the splint remains intact so that it can function as a hinge. See for example column 4, lines 1-5, stating that in the preferred embodiment, the latitudinal welds do not extend across the entire width of the splint so that a center portion of the splint remains undivided; column 4, lines 53-61, stating that the center portion shown in Fig. 1a serves as a flexure upon which the two U-shaped portions 50, 60 bend toward or away from one another; and column 6, lines 27-29, stating that the center portions shown in Fig. 6 serve to couple the rows of air chambers together and thus keep the splint as "one integral piece."

For the reasons given above, Shah et al. is not prior art.

The examiner contends it would have been obvious to modify the compression device in either Rotta or Lee et al. to use perforations as taught by Islava or Shah. Applicants respectfully disagree. As explained above, Shah is not prior art. As to Islava, the express purpose of Islava's splint is to immobilize and stabilize an injured limb, particularly a bent limb as shown in Figs. 3 and 4 (see col. 1, lines 54-61; col. 5, lines 1-5). To do this, the splint is designed to "encompass" and "envelop" the joint after the splint is partially torn (see col. 4, lines 27-31 and col. 5, lines 18-21). Clearly, the hinge portion 29 assists in achieving these objectives, i.e., immobilizing, stabilizing, encompassing and enveloping the joint after the splint is partially torn to form two U-structures. On the other hand, tearing through the hinge portion 29 and thus destroying it would eliminate the ability of the splint to immobilize, stabilize, encompass and envelop the injured limb at the joint.

Moreover, the skilled person would recognize that if Islava's perforated weld 40 were extended to run continuously across the splint from one side of the splint to an opposite side of the splint, i.e., through the hinge 29, the splint could not be properly

inflated because the weld 40 would block the flow of air into the air chambers located on the side of the weld opposite the blow spout 18. Alternatively, if an air passage was provided across the weld to allow inflation of all air chambers, then tearing along the perforations would breach the passage and the entire splint would deflate. In short, any attempt to extend the perforated weld 40 completely across the splint would render the splint inoperable for its intended purpose. (See MPEP 2143.01(V) stating that "If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification.) For this additional reason, Islava cannot possibly teach a complete separation of the portions 50, 60 from one another.[3]

Still further, the claimed invention has achieved a surprising result. Normally, tearing an article apart destroys the unity of the device and its functionality. However, applicant has used what would ordinarily be considered to be a destructive action and turned it into an advantage. Specifically, applicants have invented a compression sleeve which is intentionally designed to be torn apart, thereby irreversibly destroying the unity of the sleeve, while still leaving one portion intact and capable of carrying out sequential compression on the limb of a patient. The surprising and unpredictable nature of this result is strong evidence of non-obviousness. *KSR International Co. v. Teleflex Inc.*

The benefits of the present invention include greater comfort for the patient and reduced cost to the hospital. For example, using a line of perforations instead of releasable mechanical connectors of the type shown in the cited prior art allows applicants' compression sleeve to be manufactured as a one-piece sleeve. As a result, the product is cheaper and easier to use because there is no need to connect, disconnect and/or re-connect a series of separate segments. A patient may be prescribed a mixed vascular therapy starting with the use of a full-length compression sleeve, followed by a period of time using a knee-length sleeve. With the tear-away perforations of the present

[3] Islava states in column 4, lines 21-24, that "If a single latitudinal weld 40 were provided to extend across the entire width of the splint, the perforation may also extend through the entire width of the splint 10." However, there is no disclosure that any such perforated weld would be "continuous", as claimed by applicant, or that any such perforated weld could be used to completely remove one section of the splint from another section. On the contrary, as discussed above, the patent emphasizes the importance of keeping the un-welded center portion of the splint intact so that it can function as a hinge. Further, as discussed above, a continuous weld completely across the splint would create a non-functional product.

invention, there is no need for the hospital to replace the full-length sleeve with a new knee-length sleeve. The patient can use the same sleeve (with the thigh portion removed) to complete the prescribed sequential compression vascular therapy. Removal of a portion of the sleeve also increases the comfort and mobility of the patient. These many advantages further support the non-obviousness of the claimed invention.

Claims 8-10, 14-17, 22, 24-26, and 28 are rejected under 35 USC 103 as unpatentable over either Rotta (US 3,862,629) or Lee et al. (US 3,826,249) in view of either Islava (6,719,711) and Shah et al. (US 6,984,215) and further in view of Dye (US 5,795,312).

These claims are allowable for the same reasons as claim 1. Dye shows a compression sleeve with a plurality of longitudinally disposed inflatable chambers 38a-38f. Dye fails to disclose perforations extending across the sleeve to allow the sleeve to be completely torn to remove one portion from the other.

Further, claims 14, 24 and 26 state that the thigh and calf portions of the sleeve are connected by a flexible section of reduced width having a knee opening therein, and that the perforations extend across the flexible section at a location below the knee opening. While it is true that Dye discloses a knee opening, Dye does not suggest where to locate perforations relative to the knee opening.

Claims 29-31 are rejected under 35 USC 103 as unpatentable over either Rotta (US 3,862,629) or Lee et al. (US 3,826,249) in view of either Islava (6,719,711) and Shah et al. (US 6,984,215) and further in view of Mitchell (US 2,638,915).

These claims are allowable for the same reasons as claim 1, in that none of the references, including Mitchell, teaches irreversible tearing of a compression sleeve along a line of perforations, as claimed.

The examiner cites Mitchell as teaching (in Fig. 1) a connector in which the downstream tubular pathways 14, 18 have quick disconnect ports 60 for individually disconnecting the downstream tubular pathways as desired or required. However, Mitchell fails to show or suggest a single connector connecting a first tubing, a second tubing and a third tubing to respective expandable chambers, as required by claim 28. Further, when the disconnect ports 60 are disconnected from the coupling unit 10, the

valve members 98, 140 close to seal the coupling sections 59, 60 and the detached conduit sections 12, 14 (column 8, lines 60-64). There is no flow through the closed valve members 98 after disconnection. This is in direct contradiction to claims 29 and 30 which state that the connector comprises a fluid port and a valve for only partially closing the fluid port when the first tubing leading to the tear-away portion of the sleeve is removed from the connector. This partial-closure feature is advantageous because it allows continued flow through the port vacated by the first tubing to maintain continuity with the pressurized fluid source so that vascular therapy can continue without interruption after the first portion of the sleeve is removed by tearing along the perforations.

Claims 1, 3-11, 13-20, 22, 24-26, and 28-31 are rejected under 35 USC 103 as unpatentable over Dye (US 5,795,312) in view of either Rotta (US 3,862,629) or Lee et al. (US 3,826,249) and Islava (6,719,711) or Shah et al. (US 6,984,215) and Arkans (U.S. 6,062,244).

These claims are allowable for the same reasons as claim 1, in that none of the references, including Arkans, teaches irreversible tearing of a compression sleeve along a line of perforations, as claimed.

The examiner contends that it would have been obvious in view of either Rotta or Lee et al. to separate different parts of Dye's sleeve from one another in order to accommodate different needs of different patients, and that it would have been obvious in view of Islava et al. or Shah et al. to separate the parts to using perforation. Applicants disagree. As explained above, Islava's perforations do not extend completely and continuously across the splint. Rather, the perforations are configured for allowing two U-structures to be independently formed and moved while remaining connected by the hinge 29. Thus, Islava actually teaches away from modifying Dye as the examiner contends. Further, as explained above, Shah et al. is not prior art.

The examiner also cites the Arkans patent, but Arkans is completely devoid of any teaching of a perforation to tear a first sleeve portion from a second sleeve portion. Accordingly, this reference cannot make the claimed invention obvious.

Claim 28, which depends from claim 1, defines patentable subject matter for the additional reason that it is directed to a specific and unique tubing/connector/quick disconnect port arrangement. This arrangement comprises a single connector for connecting a pressurized fluid source to a first tubing, a second tubing and a third tubing for delivering pressurized fluid from the source to respective first, second and third expandable chambers. Further, the first tubing comprises a quick disconnect port (e.g., at 70 in Fig. 3 of the application) to permit easy removal of the first tubing from a downstream side of the connector when the first portion of the sleeve is removed from the second portion of the sleeve.

The examiner argues that Arkans discloses a similar arrangement. However, in Arkans, the two downstream tubes 50a, 50b supplying fluid to the cuffs 36, 38 remain attached to the downstream connector 44 at all times. There is no disclosure or suggestion whatsoever that one tube can be removed from the downstream side of the connector 44.

The connector/tubing/quick disconnect port arrangement of claim 28 is efficient, economical, and allows the first portion of the sleeve to be easily removed from the second portion of the sleeve. Accordingly, claim 28 is submitted as patentable for this addition reason.

Claim 29 includes the connector/tubing/quick disconnect port arrangement of claim 28 and is allowable for all of the same reasons. In addition, claim 29 states that the connector comprises a fluid port and a valve which functions to only partially close the fluid port when the first tubing leading to the tear-away portion of the sleeve is removed from the connector. Because the valve only partially closes, fluid is able to continue to flow from the fluid port, and inflation and deflation of the two (or more) chambers in the second portion of the sleeve may continue without interruption. In this regard, feedback information to the controller is necessary to achieve proper operation. If a portion of the sleeve is removed, this feedback is interrupted and would normally cause the controller to discontinue operation. However, when the sleeve is equipped with the valve connector of claim 29, pressurized fluid continues to flow through the fluid port even after a portion of the sleeve is torn away and the associated tubing is disconnected from the fluid port of the connector. This continued flow simulates the flow characteristics prior to such

disconnection so that the controller continues to operate as if the disconnection had not occurred. (For further details of this valve connection, see page 8, lines 12, lines 6-15 of the present application and Application Ser. No. 10/784,639, published August 25, 2005 as Publication No. 2005/01842645, incorporated by reference in this application).

The tubing/connector/valve feature of claim 29 is not shown or suggested by the prior art for the same reasons expressed above in regard to claim 28. Further, these references are completely devoid of any showing or suggestion of a connector comprises a fluid port and a valve for only partially closing the fluid port when the first tubing leading to the tear-away portion of the sleeve is removed from the connector. For this additional reason, claim 29 is allowable.

Claim 30 depends from claim 29 and states that the valve of the connector is movable when the first tubing is removed from the connector to reduce fluid flow from the pressurized fluid source through the fluid port of the connector to a level approximating flow to the first expandable chamber prior to removal of the first portion of the sleeve from the second portion of the sleeve. As discussed above, this feature is advantageous because it maintains continuity with the pressurized fluid source so that vascular therapy can continue without interruption after the first portion of the sleeve is removed by tearing along the perforations. (See page 12, lines 6-15 of the present application.) There is no disclosure or suggestion of this feature in the cited prior art.

Claims 12 and 28-30 are rejected under 35 USC 103 as unpatentable over Dye (US 5,795,312) in view of either Rotta (US 3,862,629) or Lee et al. (US 3,826,249) and Islava (6,719,711) or Shah et al. (US 6,984,215) and further in view of Mitchell (US 2,638,915).

These claims are allowable for the same reasons as claim 1, in that none of the references teach irreversible tearing of a compression sleeve along a line of perforations, as claimed.

Further, the examiner argues it would have been obvious in view of Mitchell to modify Dye to include a coupling means so that one can disconnect the tubular pathway to the first portion of the sleeve and still be able to operate the second portion by itself. However, Mitchell fails to show or suggest a single connector connecting a first tubing, a

second tubing and a third tubing to respective expandable chambers, as required by claim 28. Moreover, when Mitchell's disconnect ports 60 are disconnected from the coupling unit 10, the valve members 98, 140 close to seal the coupling sections 59, 60 and the detached conduit sections 12, 14 (column 8, lines 60-64). There is no flow through the closed valve members 98 after disconnection. This is in direct contradiction to claims 29 and 30 which state that the connector comprises a fluid port and a valve for only partially closing the fluid port when the first tubing leading to the tear-away portion of the sleeve is removed from the connector. As discussed above, applicants' claimed valve feature is advantageous because allowing continued flow through the port vacated by the first tubing maintains continuity with the pressurized fluid source so that vascular therapy can continue without interruption after the first portion of the sleeve is removed by tearing along the perforations.

Applicants' Arguments regarding Claims 28-30 Have Not Been Addressed

In the response filed December 17, 2008, applicants made several specific points rebutting the rejection of claims 28-30 under 35 USC 103. In particular, applicants explained on pages 23-25 why Mitchell 2,638,915 and Arkans 6,062,244 fail to show or suggest, among other things, a quick disconnect port for easy removal of the first tubing from a downstream side of the connector when the first portion of the sleeve is removed from the second portion of the sleeve (claim 28), a valve in the connector for partially closing the fluid port when the tubing is removed so that fluid can continue to flow from the fluid port (claim 29), and movement of the valve after removal to reduce fluid flow to a level approximating the flow level prior to removal (claim 30). This explanation has not been addressed in the Office action, and applicants are concerned that it may have been overlooked.[4]

Notice of Appeal

Applicants submit a Notice of Appeal with this response to the Office action.

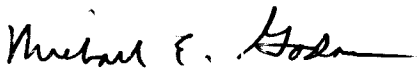
[4] The rejection of claims 28-30 in the most recent action merely repeats the same grounds asserted in the previous action without addressing the additional points made in applicants' last response.

CONCLUSION

In view of the foregoing, applicants request withdrawal of the final rejection and allowance of the application. The above arguments were not presented earlier because they are responsive to issues raised for the first time in the Office action dated April 17, 2009.

The Commissioner is hereby authorized to charge a two-month extension of time and credit any overpayment to Deposit Account No. 190254. Applicants are filing a Notice of Appeal with this Letter to the Patent and Trademark Office after Final Rejection. Applicants request that **only one** 2-month extension fee be charged to Deposit Account No. 19-0254 for the filing of these two documents.

Respectfully submitted,



Michael E. Godar, Reg. No. 28,416
SENNIGER POWERS LLP
100 North Broadway, 17th Floor
St. Louis, Missouri 63102
(314) 231-5400

MEG/bcw